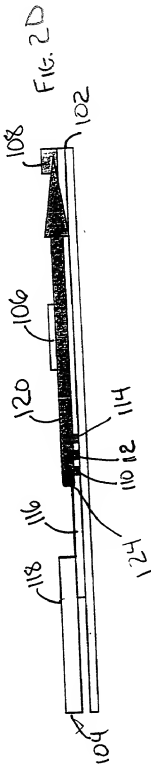
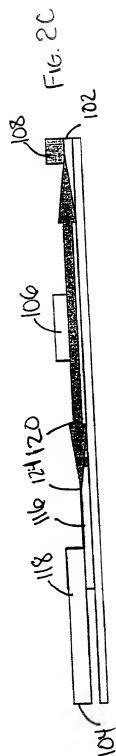
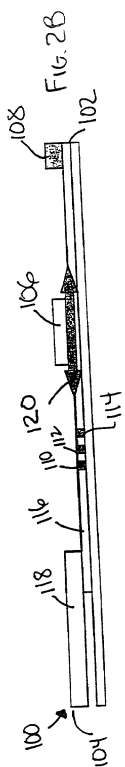
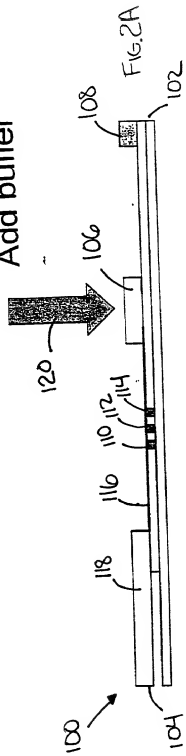
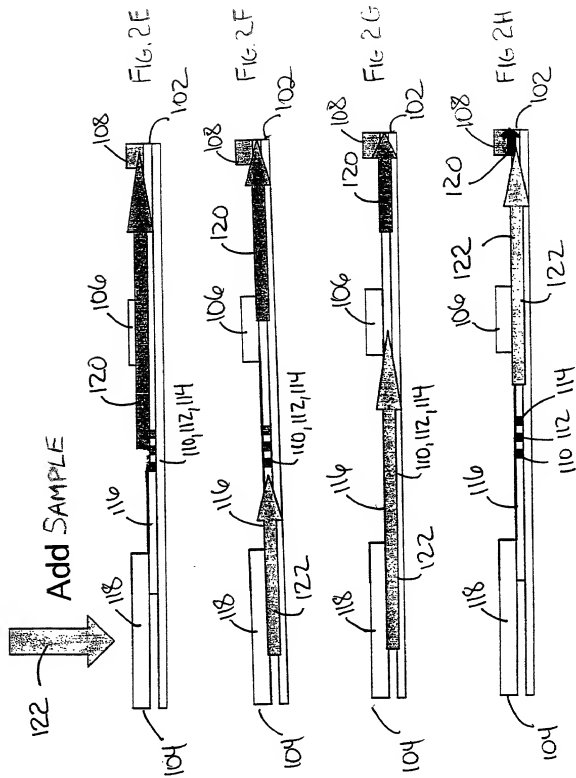


Add buffer





Add sample

Add buffer

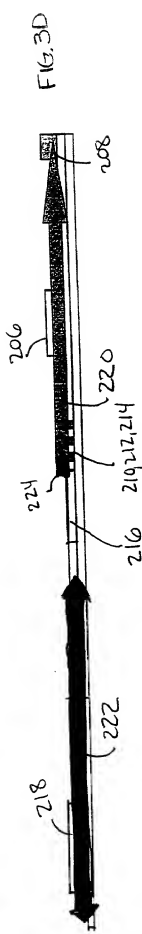
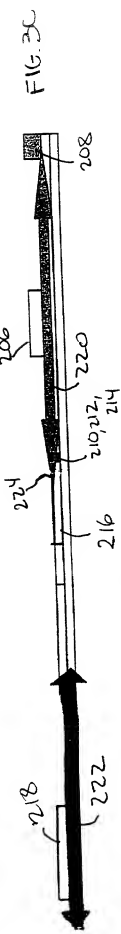
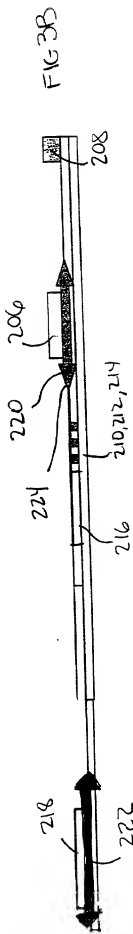
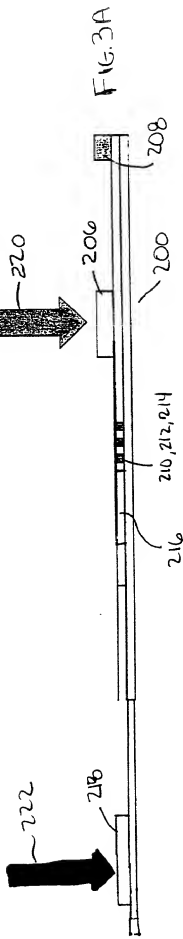


FIG. 3E

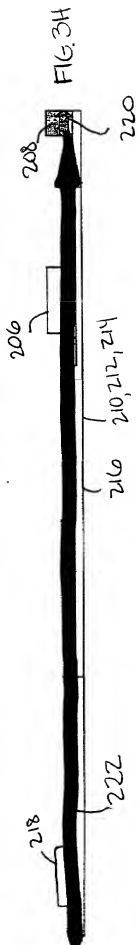


FIG. 4

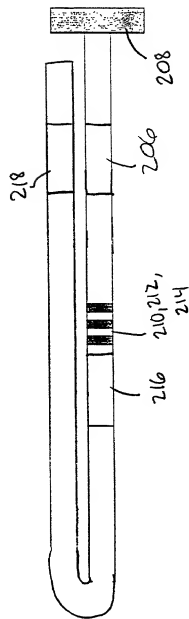


FIG. 5A

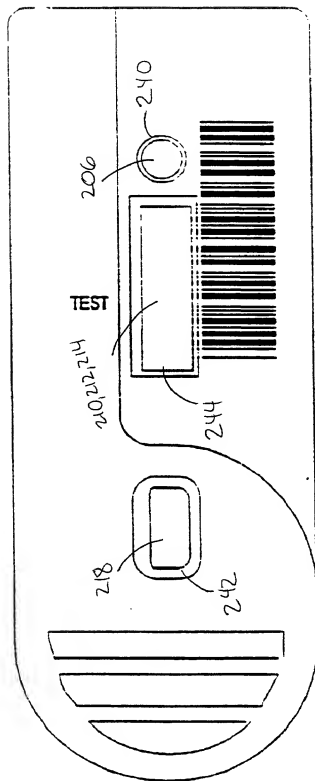


FIG. 5B

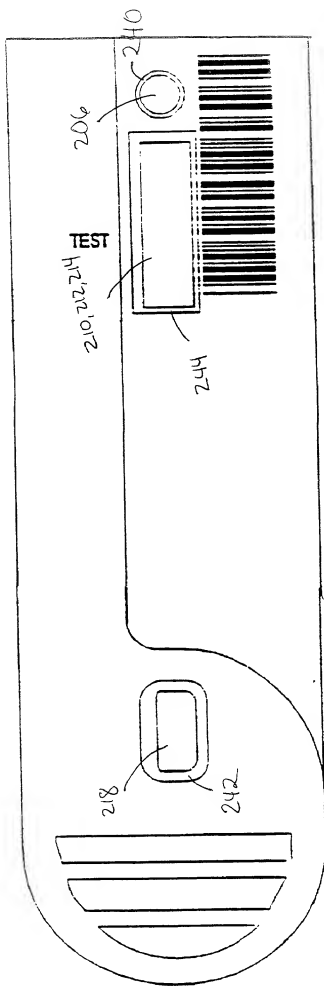


FIG. 5C

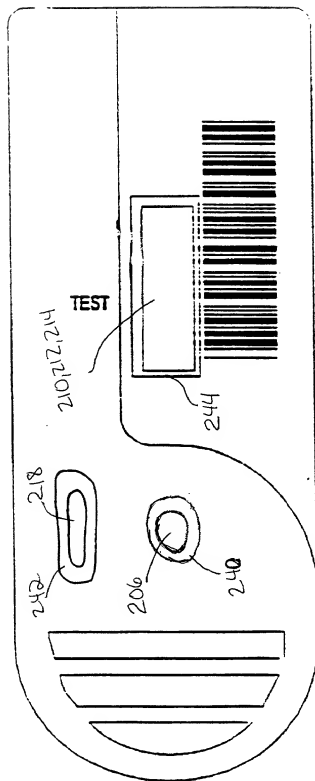


FIG. 6A

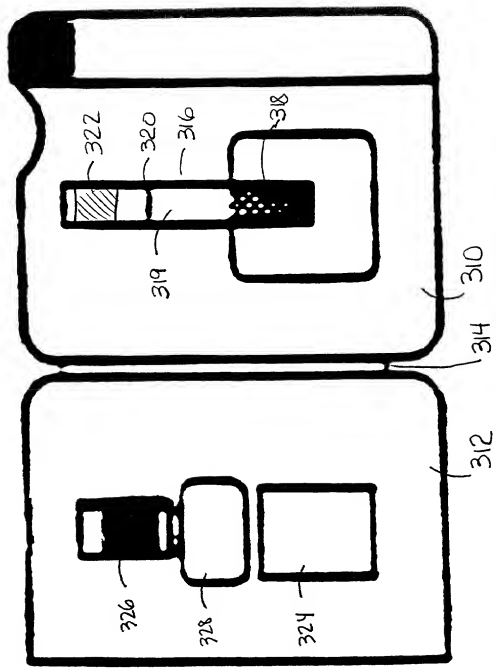
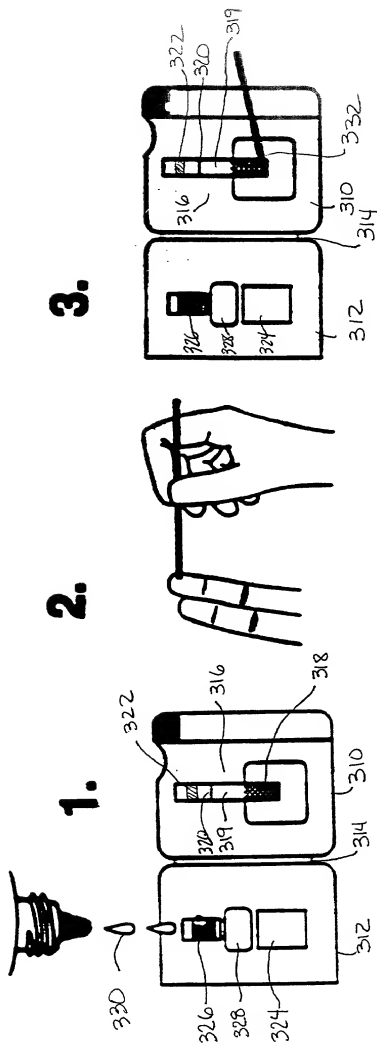


FIG. 6B



ReLIA™ TSH (Goat Capture) 160 µg/ml BSA-DNP in Release Buffer

FIGURE 8

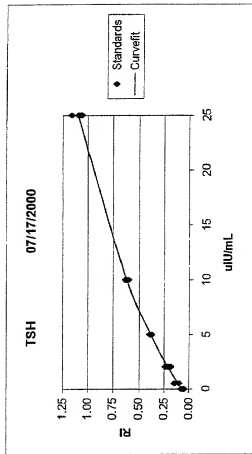
Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/Hc	uIU/ml
4A	58R	104	0.3229	0.2308	0.2153	1.399	0.6667	9.21
4A	58R	120	0.3306	0.2371	0.2073	1.394	0.6270	8.48
4A	41R	110	0.3002	0.2394	0.2010	1.254	0.6695	9.26
4A	37R	163	0.3252	0.2569	0.2112	1.266	0.6496	8.89
4A	33R	115	0.2941	0.2414	0.1942	1.218	0.6605	9.08
4A	29R	107	0.3031	0.2080	0.1980	1.457	0.6532	8.95
4A	27R	146	0.3375	0.2200	0.1980	1.534	0.5867	7.74
4A	24R	111	0.3136	0.2235	0.2010	1.403	0.6410	8.72
4A	21R	104	0.2995	0.2119	0.2024	1.413	0.6755	9.37
4A	18R	120	0.3213	0.2291	0.1959	1.403	0.6097	8.16
4A	14R	110	0.2802	0.2105	0.1917	1.378	0.6607	9.10
4A	12R	163	0.3176	0.2333	0.2128	1.361	0.6699	9.27
4A	9R	115	0.3156	0.2243	0.2050	1.407	0.6494	8.88
4A	7R	107	0.3170	0.2213	0.2140	1.432	0.6751	9.37
4A	4R	146	0.3367	0.2329	0.2110	1.446	0.6265	8.46
4A	3R	111	0.3409	0.2426	0.2237	1.405	0.6562	9.01
AVG			0.3166	0.2289	0.2052	1.3856	0.6486	8.87
STD DEV			0.0158	0.0132	0.0089	0.0799	0.0250	0.46
%CV			5.0	5.7	4.3	5.8	3.9	5.2

TSH (RI = antigen Dr/Hc Dr)

7/17/2000

FIGURE 9

Standard	RI	Standards	Fitted RI
0.0	0.046	0	0.050
0.0	0.049	0.5	0.104
0.0	0.058	2.0	0.210
0.0	0.078	5.0	0.384
0.5	0.094	10.0	0.618
0.5	0.0945	25.0	1.098
0.5	0.0955		
0.5	0.1471		
2.0	0.1801		
2.0	0.2365		
2.0	0.2146		
2.0	0.1970		
5.0	0.3889		
5.0	0.3788		
5.0	0.3926		
5.0	0.3730		
10.0	0.6198		
10.0	0.6262		
10.0	0.6301		
10.0	0.6026		
25.0	1.0938		
25.0	1.0580		
25.0	1.0755		
25.0	1.1618		



chi-squared

0.57

K0 48.7910

K1 0.9165

K2 2.9872

K3 0.0604

Standards: 0 uIU/ml 0.5 uIU/ml 2 uIU/ml 5 uIU/ml 10 uIU/ml 25 uIU/ml

0.046 0.094 0.1801 0.3889 0.6198 1.0938

0.049 0.0945 0.2365 0.3788 0.6262 1.0580

0.058 0.0995 0.2146 0.3926 0.6301 1.0755

0.078 0.1471 0.1970 0.3730 0.6026 1.1618

Mean: 0.058 0.109 0.207 0.383 0.620 1.097

SD: 0.014 0.026 0.024 0.009 0.012 0.046

CV 24.62 23.67 11.57 2.35 1.96 4.14

Standards: 0 uIU/ml 0.5 uIU/ml 2 uIU/ml 5 uIU/ml 10 uIU/ml 25 uIU/ml

0.00 0.37 1.56 5.08 10.036 24.850

0.00 0.38 2.42 4.894 10.191 23.443

0.00 0.45 2.08 5.155 10.286 24.124

0.18 1.08 1.81 4.786 9.626 27.650

Mean: 0.046 0.570 1.967 4.980 10.035 25.027

SD: 0.092 0.342 0.372 0.170 0.291 1.866

CV 200.00 59.91 18.90 3.42 2.90 7.46

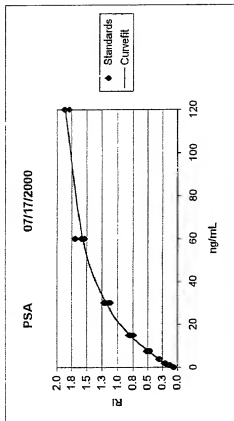
ReLIA™ PSA (Goat Capture) 160 µg/ml BSA-DNP in Release Buffer

FIGURE 10

Sample	Sheet	Instrument	Hc (Dr)	Lc (Dr)	Specimen (Dr)	Hc/Lc	Specimen/Hc	ng/ml
2A	HF 135-24	163	0.2438	0.2469	0.1206	0.987	0.4948	9.70
2A	HF 135-23	165	0.2243	0.2252	0.0969	0.996	0.4318	8.20
2A	HF 135-20	104	0.2883	0.2543	0.1352	1.134	0.4690	9.07
2A	HF 135-21	120	0.2188	0.2165	0.0996	1.011	0.4553	8.75
2A	HF 135-31	115	0.2448	0.2113	0.1123	1.159	0.4586	8.83
2A	HF 135-30	107	0.2301	0.2283	0.1177	1.008	0.5117	10.11
2A	HF 135-27	111	0.2149	0.1825	0.1094	1.177	0.5089	10.05
2A	HF 135-25	146	0.2329	0.2206	0.1078	1.056	0.4629	8.93
2A	HF 135-36	163	0.2907	0.2558	0.1342	1.136	0.4617	8.90
2A	HF 135-35	165	0.3104	0.2988	0.1237	1.039	0.3984	7.45
2A	HF 135-33	104	0.2467	0.2507	0.1133	0.984	0.4595	8.85
2A	HF 135-34	120	0.2424	0.2270	0.1288	1.068	0.5313	10.62
2A	HF 135-18	115	0.2535	0.2529	0.1150	1.002	0.4535	8.71
2A	HF 135-37	107	0.2784	0.2633	0.1300	1.057	0.4672	9.02
2A	HF 135-19	111	0.2702	0.2701	0.1158	1.000	0.4288	8.14
2A	HF 135-29	146	0.2624	0.2314	0.1185	1.134	0.4515	8.66
AVG			0.2533	0.2397	0.1174	1.0593	0.4653	9.00
STD DEV			0.0279	0.0275	0.0112	0.0673	0.0334	0.80
%CV			11.0	11.5	9.5	6.4	7.2	8.9

PSA
0706-HF135

Figure 11



0.0 0.0713
0.0 0.0906
0.0 0.0941
0.0 0.0511
1.0 0.1178
1.0 0.1128
1.0 0.1754
1.0 0.1501
1.0 0.1202
1.0 0.1432
2.0 0.1927
2.0 0.1832
2.0 0.2127
4.0 0.2952
4.0 0.2906
4.0 0.3007
4.0 0.2891
7.5 0.4709
7.5 0.5187
7.5 0.4582
7.5 0.5072
15.0 0.8110
15.0 0.7819
15.0 0.7861
15.0 0.7392
30.0 1.2190
30.0 1.1140
30.0 1.1931
30.0 1.1507
60 1.5443
60 1.5863
60 1.5426
60 1.6945
120 1.7872
120 1.8674

Chi-squared

1.53

RI

0 ng/ml 1 ng/ml 2 ng/ml 4 ng/ml 7.5 ng/ml 15 ng/ml 30 ng/ml 60 ng/ml 120 ng/ml
0.0713 0.1178 0.1927 0.3082 0.4709 0.8110 1.2190 1.5443 1.8674
0.0606 0.1126 0.1832 0.2926 0.5187 0.7819 1.1140 1.5863 1.8674
0.0641 0.1754 0.1933 0.3007 0.4582 0.7861 1.1931 1.5466 1.8674
0.0511 0.1501 0.2127 0.2891 0.5072 0.7392 1.1507 1.5945 1.8674

Mean 0.092 0.139 0.180 0.298 0.483 0.779 1.169 1.595 1.827
SD 0.01 0.03 0.01 0.01 0.03 0.03 0.05 0.03 0.06
CV 13.59 21.16 2.99 2.87 6.61 3.88 3.96 1.90 3.10

ng/ml

0 ng/ml 1 ng/ml 2 ng/ml 4 ng/ml 7.5 ng/ml 15 ng/ml 30 ng/ml 60 ng/ml 120 ng/ml
0.00 0.00 0.79 2.09 4.14 7.29 15.63 31.95 57.56 98.70
0.00 0.00 0.70 1.93 3.86 8.29 14.79 26.72 62.64 125.63
0.00 0.00 1.79 2.10 4.00 7.02 14.91 30.57 57.36 97.36
0.00 0.00 1.36 2.44 3.79 8.05 13.58 28.44 79.25 124.44

Mean
SD
CV

0.00 1.12 2.04 3.95 7.53 14.73 29.42 60.10 112.66
0.00 0.42 0.10 0.15 0.67 0.85 2.31 3.59 18.33
37.74 4.80 3.92 8.88 5.79 7.86 5.98 16.77

FIGURE 12

Comparison of ReLIA TSH Assay With Sample Added to Top and Bottom Ports Versus Sample Added to Bottom Port Only

Sample Added to Top					No Sample Added to Top				
Sample		HC DR	Specimen DR	$\frac{\text{Specimen DR}}{\text{HC DR}}$ TSH (uIU/mL)	HC DR	Specimen DR	$\frac{\text{Specimen DR}}{\text{HC DR}}$ TSH (uIU/mL)		
S-25 Spiked	Mean	0.2469	0.0243	0.0973	1.9088	0.204	0.0249	0.1252	2.4425
	SD	0.0154	0.017	0.0054	0.101	0.0359	0.007	0.0292	0.5275
	CV	6.2%	7.0%	5.5%	5.3%	17.6%	2.9%	23.1%	21.6%
S-42 Spiked	Mean	0.2555	0.0869	0.3399	6.2571	0.2219	0.0855	0.4055	7.4928
	SD	0.0199	0.0054	0.0275	0.4681	0.0249	0.0057	0.0281	0.5252
	CV	7.8%	6.3%	8.1%	7.9%	11.2%	6.4%	6.9%	7.0%
Pod A	Mean	0.2541	0.1369	0.5435	10.1692	0.2338	0.1394	0.6035	11.418
	SD	0.0312	0.0083	0.0467	1.0065	0.0362	0.0133	0.0575	1.4461
	CV	12.3%	6.8%	9.2%	9.9%	15.5%	9.6%	11.2%	12.7%
Pod B	Mean	0.2613	0.0031	0.1165	2.308	0.2147	0.0289	0.1358	2.6254
	SD	0.0164	0.0021	0.0082	0.1525	0.0289	0.0025	0.0128	0.2335
	CV	6.3%	6.8%	6.9%	6.6%	13.4%	8.7%	9.4%	8.9%

FIGURE 13

Reproducibility of the ReLIA TSH Assay With Sample added to Top and Bottom

TSH LEVEL

ReLIA Result in uIU/mL (N = 8 Replicates)

Normal (Approx. 1 uIU/mL)	Mean	1.0712
	SD	0.089
	CV	8.3%
Borderline Elevated (Approx. 5 uIU/mL)	Mean	6.2425
	SD	0.551
	CV	8.8%
Elevated (Approx. 25 uIU/mL)	Mean	23.631
	SD	1.658
	CV	7.0%

FIGURE 14

